Amendments to the Claims

This listing of claims replaces all prior versions of claims in the application:

1. (Currently amended) A pharmaceutical dosage form suitable for oral administration comprising a molded microcellular polymeric material and a pharmaceutically acceptable active agent, and wherein the molded microcellular polymeric material is a non-thermosetting polymerized plastics material comprised of at least one polyol selected from lactitol, xylitol, erythritol, sorbitol, maltitol, or mannitol, or combinations thereof; and
at least one of

a) non-thermosetting modifier selected from a starch, maltodextrin, a dextrose equivalent, polyalditol, a hydrogenated starch hydrosylate, or a mixture thereof; and/or

b) a non-thermosetting polymer selected from carboxymethyl cellulose sodium, methyl cellulose, ethylcellulose, hydroxyethylcellulose (HEC), hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, noncrystalline cellulose, starch and its derivatives, and sodium starch glycolate or mixtures thereof.

2. -3. (Cancelled)

4. (Currently amended) The pharmaceutical dosage form according to claim [[3]] 1 wherein the non-thermosetting polymerized plastics material contains at least one polyol, and at least one non-thermosetting modifier.

5. – 6. (Cancelled)

7. (Currently amended) The pharmaceutical dosage form according to claim [[6]] 1 wherein the starch is pregelatinized corn starch, corn starch, potato starch, rice starch, hydroxyethyl starch, wheat starch, tapioca starch, or waxy maize starch, or mixtures thereof.

8. (Currently amended) The pharmaceutical dosage form according to claim [[6]] 1 wherein the non-thermosetting modifier is a maltodextrin.

9. – 10. (Cancelled)

11. (Currently amended) The pharmaceutical dosage form according to claim [[10]] wherein the disintegrant is croscarmellose sodium, sodium starch glycolate, sodium carboxymethyl-cellulose, [[Ac-di-sol®,]] carboxymethyl-cellulose, veegum, an alginate, agar, guar, tragacanth, locust bean, karaya, pectin, or crospovidone.

12. (Currently amended) The pharmaceutical dosage form according to claim [[10]] 1 wherein the lubricant is glycerol monostearate, stearyl alcohol NF, stearic acid NF, ~~Cab-O-Sil, Syloid~~ colloidal silicon dioxide, silica gel, zinc stearate USP, magnesium stearate NF, calcium stearate NF, sodium stearate, cetostrearyl alcohol NF, sodium stearyl fumerate NF, or talc.

13. (Currently amended) The pharmaceutical dosage form according to claim [[10]] 1 wherein the ~~opacifiers~~ opacifier is talc USP, calcium carbonate USP, or kaolin USP.

14. (Original) The pharmaceutical dosage form according to claim 1 wherein the pharmaceutically acceptable active agent is selected from an analgesic, an anti-inflammatory agent, an anthelmintic, anti-arrhythmic, antibiotic, anticoagulant, antidepressant, antidiabetic, antiepileptic, antihistamine, antihypertensive, antimuscarinic, antimycobacterial, antineoplastic, immunosuppressant, antithyroid, antiviral, anxiolytic and sedatives, beta-adrenoceptor blocking agents, cardiac inotropic agent, corticosteroid, cough suppressant, diuretic, dopaminergic, immunological agent, lipid regulating agent, muscle relaxant, parasympathomimetic, parathyroid, calcitonin and biphosphonates, prostaglandin, radiopharmaceutical, anti-allergic agent, sympathomimetic, thyroid agent, PDE IV inhibitor, CSBP/RK/p38 inhibitor, and a vasodilator.

15. – 19. (Cancelled)

20. (Currently amended) The pharmaceutical dosage form according to claim 1 wherein the microcellular polymeric material results in [[is]] a closed cell foam.

21. (Currently amended) A pharmaceutical dosage form comprising: a rigid microcellular foam consisting of a solid excipient having voids of substantially uniform size with a maximum void dimension in the range from about 2 to 100 microns and a void fraction in the range of about 5 to 95 percent, the solid excipient comprising ~~a non-thermosetting polymerized plastic material and~~ an active pharmaceutical agent combined in a homogeneous solid mixture with a non-thermosetting polymerized plastic material comprised of at least one polyol selected from lactitol, xylitol, sorbitol, erythritol, maltitol, or mannitol, or combinations thereof; and

at least one of

a) non-thermosetting modifier selected from a starch, maltodextrin, a dextrose equivalent, polyalditol, a hydrogenated starch hydrosylate, or a mixture thereof; and/or

b) a non-thermosetting polymer selected from carboxymethyl cellulose sodium, methyl cellulose, ethylcellulose, hydroxyethylcellulose (HEC), hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, noncrystalline cellulose, starch and its derivatives, and sodium starch glycolate or mixtures thereof; and

which optionally comprises a sweetener, a disintegrant, a binder, a lubricant, or an opacifier; and

optionally further comprises a sweetener, a disintegrant, a binder, a lubricant, or an opacifier.

22. (Cancelled)

23. (Currently amended) The pharmaceutical dosage form according to claim 21 wherein the polyol is lactitol, ~~xylitol, sorbitol, maltitol,~~ erythritol or mannitol, or combinations thereof.

24. (Currently amended) The pharmaceutical dosage form according to claim 21 wherein the non-thermosetting modifier is a starch, or maltodextrin, ~~a dextrose equivalent, polyalditol , a hydrogenated starch hydrosylate,~~ or a mixture thereof.

25. (Original) The pharmaceutical dosage form according to claim 24 wherein the starch is pregelatinized Corn Starch, Corn Starch, Potato starch, Rice starch, hydroxyethyl starch, Wheat starch, Tapioca starch, or Waxy maize starch.

26. (Currently amended) The pharmaceutical dosage form according to claim [[22]] 21 wherein the nonthermosetting modifier is a maltodextrin.

27. (Currently amended) The pharmaceutical dosage form according to claim 21 wherein the non-thermosetting polymer is present in an amount of 2 to 90 % w/w ~~carboxymethyl cellulose sodium, methyl cellulose, ethylcellulose, hydroxyethylcellulose (HEC), hydroxypropylmethyl cellulose (HPMC), hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, nonerystalline cellulose, starch and its derivatives, and sodium starch glycolate or mixtures thereof~~.

28. (Cancelled)

29. (Currently amended) The pharmaceutical dosage form according to claim [[28]] 21 wherein the disintegrant is croscarmellose sodium, sodium starch glycolate, sodium carboxymethyl-cellulose,[[Ac-di-sol®,]] carboxymethyl-cellulose, veegum, an alginate, agar, guar, tragacanth, locust bean, karaya, pectin, or crospovidone.

30. (Currently amended) The pharmaceutical dosage form according to claim [[28]] 21 wherein the lubricant is glycerol monostearate, stearyl alcohol NF, stearic acid NF, ~~Cab-O-Sil, Syloid~~ colloidal silicon dioxide, silica gel, zinc stearate USP, magnesium stearate NF, calcium stearate NF, sodium stearate, cetostrearyl alcohol NF, sodium stearyl fumerate NF, or talc.

31. (Currently amended) The pharmaceutical dosage form according to claim [[28]] 21 wherein the ~~opacifiers~~ opacifier is talc USP, calcium carbonate USP, or kaolin USP.

32. (Original) The pharmaceutical dosage form according to claim 21 wherein the active pharmaceutical agent is selected from an analgesic, an anti-inflammatory agent, an anthelmintic, anti-arrhythmic, antibiotic, anticoagulant, antidepressant, antidiabetic, antiepileptic, antihistamine, antihypertensive, antimuscarinic, antimycobacterial, antineoplastic, immunosuppressant, antithyroid, antiviral, anxiolytic and sedatives, beta-adrenoceptor blocking agents, cardiac inotropic agent, corticosteroid, cough suppressant, diuretic, dopaminergic, immunological agent, lipid regulating agent, muscle relaxant, parasympathomimetic, parathyroid, calcitonin and biphosphonates, prostaglandin, radiopharmaceutical, anti-allergic agent, sympathomimetic, thyroid agent, PDE IV inhibitor, CSBP/RK/p38 inhibitor, and a vasodilator.

33- 36. (Cancelled)

37. (Previously presented) The pharmaceutical dosage form according to claim 21 wherein the microcellular polymeric material is a closed cell foam.

38. (Original) A pharmaceutical dosage form according to claim 21, in which the homogeneous solid mixture has a sufficiently high solubility in saliva that the dosage form dissolves substantially immediately in the mouth upon oral administration.

39. (Original) A pharmaceutical dosage form according to claim 21, in which the voids are in the form of closed cells.

40. (Original) A pharmaceutical dosage form according to claim 21, in which the rigid microcellular foam is enclosed within a skin having a density substantially greater than that of the microcellular foam, but having the same composition as that of said solid mixture.

41. (Original) A pharmaceutical dosage form according to claim 21, in which the overall density of the dosage form is substantially less than that of stomach fluids, whereby the dosage form is gastro-retentive.

42. to 50. (Cancelled)

51. (New) The pharmaceutical dosage form according to claim 27 wherein the non-thermosetting modifier is present in an amount of from 5 to 50% w/w.

52. (New)The pharmaceutical dosage form according to claim 21 wherein the wherein the polyol is present in an amount of from 5% to 70% w/w.

53. (New)The pharmaceutical dosage form according to claim 21 wherein the wherein the polyol is present in an amount of from 5 to 50% w/w.

54. (New)The pharmaceutical dosage form according to claim 21 wherein the wherein the polyol is present in an amount of from 5 to 25% w/w.

55. (New) The pharmaceutical dosage form according to claim 1 wherein the non-thermosetting modifier is present in an amount of from 2 to 90% w/w.

56. (New) The pharmaceutical dosage form according to claim 55 wherein the non-thermosetting modifier is present in an amount of from 5 to 50% w/w.

57. (New) The pharmaceutical dosage form according to claim 1 wherein the wherein the polyol is present in an amount of from 5% to 70% w/w.

58. (New) The pharmaceutical dosage form according to claim 21 wherein the wherein the polyol is present in an amount of from 5 to 50% w/w.

59. (New) The pharmaceutical dosage form according to Claim 1 which is:

Example #	Formulation	w/w%
1	Xylitol Hydroxypropyl cellulose, Grade EF Croscarmellose Sodium Glycerol monostearate	25% 69% 5% 1%
2	Hydroxypropyl cellulose, Grade EF Glycerin Glycerol monostearate	90.0% 7.5% 2.5%
3	Lactitol Maltodextrin (Maltrin M150) Sodium Starch Glycolate	40% 50% 10%
4	Lactitol Maltodextrin (Maltrin M150) AcDiSol	40% 50% 10%
5	Lactitol Maltodextrin (Maltrin M150) Crospovidone	40% 50% 10%
6	Lactitol Maltodextrin (Maltrin M150) Pregelatinized Starch NF (Starch 1500) Crospovidone	45% 40% 5% 10%
7	Lactitol Maltodextrin (Maltrin M150) Pregelatinized Starch NF (Starch 1500) Crospovidone	50% 30% 10% 10%